

**REMARKS**

Claims presented for prosecution in this Application are claims 1-5, 7, 9-14, and 16-21. Claims 3-5, 7, 16, and 18 remain withdrawn, and claim 19 has been allowed. In view of Applicants' remarks below, Applicants respectfully submit that claims 1-2, 9-14, 17, and 20-21 are in condition for allowance. Accordingly, Applicants respectfully request that the present Response be considered and entered, the rejections to the claims be withdrawn, and that the case now be passed to issue.

***Allowable Subject Matter***

Applicants acknowledge the indication of allowable subject matter of claim 19 to the extent limited to the elected species. However, for the reasons indicated below, all pending claims are believed to be directed to allowable subject matter.

***Issues under 35 U.S.C. § 102(b)***

1) Claims 1, 2, 9-14, 17, and 20-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Paik et al., *J. Nucl. Med.*, Vol. 24, pp. 1158-1163 (1983) (see pages 3-7 of the Office Action). In response, Applicants respectfully assert that the Paik et al. reference does not disclose each and every aspect of independent claims 1 and 20-21.

Legal Standard for Determining Anticipation

“A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “When a claim covers several structures or compositions, either generically or as alternatives, the claim is deemed anticipated if any of the structures or compositions within the scope of the claim is known in the prior art.” *Brown v. 3M*, 265 F.3d 1349, 1351, 60 USPQ2d 1375, 1376 (Fed. Cir. 2001) “The identical invention must be shown in as complete detail as is contained in the ... claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Legal Standard for Determining Prima Facie Obviousness

MPEP 2141 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are:

- (a) determining the scope and content of the prior art;
- (b) ascertaining the differences between the prior art and the claims in issue;
- (c) resolving the level of ordinary skill in the pertinent art; and
- (d) evaluating any evidence of secondary considerations.

*Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

Second, the Examiner has to provide some rationale for determining obviousness. MPEP 2143 sets forth some rationales that were established in the recent decision of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007). Exemplary rationales that may support a conclusion of obviousness include:

- (a) combining prior art elements according to known methods to yield predictable results;
- (b) simple substitution of one known element for another to obtain predictable results;
- (c) use of known technique to improve similar devices (methods, or products) in the same way;
- (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (e) “obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success
- (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;
- (g) some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

As the MPEP directs, all claim limitations must be considered in view of the cited prior art in order to establish a *prima facie* case of obviousness. See MPEP 2143.03.

*Distinctions over the Prior Art*

On page 4 of the outstanding Office Action, the Examiner argues, “The claim limitation that the presence of both polyaminopolycarboxylic acid anhydride and the presence of the polyaminopolycarboxylic acid in the reaction mixture is met by the fact that the anhydride used in the preparation was a mixture of the anhydride and the free acid as shown by the IR analysis.” However, the IR analysis of Paik et al. merely suggests the presence of *a carboxylate group* but not that of *a free acid molecule of the polyaminopolycarboxylic acid since it is analyzing the IR spectrum of DTPA anhydride per se as claimed*. DTPA anhydride added in the acylation reaction by Paik et al. was not a mixture of DTPA anhydride and DTPA acid.

The Examiner recites from the teachings of Paik et al. that during the DTPA conjugation reaction, the reaction reduced the pH of the (Hepes) buffer solution to 4 due to hydrolysis of the anhydride, which produced four acetic acid molecules. Although Paik et al. disclose that, after acylation reaction with DTPA anhydride, four acetic acid moieties are present per each molecule that participated in the acylation reaction, Paik et al. do not disclose nor teach the hydrolysis of DTPA anhydride to a free DTPA acid molecule.

Paik et al. also disclose the reaction of DTPA anhydride with an amino compound, carried out in bicarbonate buffer, pH 8.2, which is in a basic condition. Thus, the Examiner appears to affirm the presence of free polyaminocarboxylic acid in the reaction mixture of Paik et al. At most, Paik et al. refer to the polyaminocarboxylic acid as above but not to the polyaminopolycarboxylic acid used in the present invention.

With the respect to the Examiner's reliance on Le Chatelier's Principle, Applicants respectfully assert that the Examiner's reasoning is beyond the disclosure of Paik et al.

Accordingly, the present invention is not anticipated by Paik et al. since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Paik et al. do not render the present invention obvious because the reference provides no disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed. Moreover, the process of Paik et al. is different from the process of the present invention. The process of the present invention provides the desired compound in a better yield than that of the process of Paik et al. as shown in the Comparative Example and Example of the present specification.

2) Claims 1, 2, 9-14, and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mease et al. '571 (US 5,021,571). In response, Applicants respectfully traverse and assert that Mease et al. '571 do not disclose each and every aspect of independent claims 1 and 21.

With respect to the disclosure of a cyclic anhydride of Mease et al. '571 as recited in the Office Action, the Examiner interprets that both the acid and the anhydride are *derived from* the same polyaminopolycarboxylic acid. The depicted molecule shows that the molecule has an anhydride moiety and an acid moiety, but they are within a single molecule.

In stark contrast, the polyaminopolycarboxylic anhydride and the polyaminopolycarboxylic acid of the present invention are independent compounds and are

different elements of the pending claims. The same polyaminopolycarboxyl group in the claims refers to a common molecular structure.

Accordingly, the present invention is not anticipated by Mease et al. '571 since the reference does not teach or provide for each of the limitations recited in the pending claims.

For completeness, Applicants also respectfully submit that Mease et al. '571 do not render the present invention obvious because the reference provides no disclosure, reason, or rationale that would allow one of ordinary skill in the art to arrive at the present invention as claimed.

### **CONCLUSION**

A full and complete response has been made to all issues as cited in the Office Action. Applicants have taken substantial steps in efforts to advance prosecution of the present application. Thus, Applicants respectfully request that a timely Notice of Allowance issue for the present case clearly indicating that each of claims 1-2, 9-14, 17, and 19-21 are allowed and patentable under the provisions of title 35 of the United States Code.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Chad M. Rink, Reg. No. 58,258 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

Dated:

DEC 12 2008

Respectfully submitted,

By

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